DEPARTMENT OF HEALTH AND HUMAN SERVICES

9344d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 7, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

IN REPLY REFER TO: SEA 02-57

Nancy F. O'Farrell, President
Wallace O'Farrell, Inc.
11302 164th Street East
Puyallup, Washington 98374

WARNING LETTER

Dear Ms. O'Farrell:

During an inspection of your facility on June 21 and 24, 2002, FDA Investigator Carl A. Anderson documented significant deviations from legal requirements in the procedures used to manufacture "Slippery Stuff," which is an over-the-counter (OTC) drug product. At the conclusion of the inspection, a FDA Form 483, Inspectional Observations, was presented to you.

Specifically, the inspection revealed that "Slippery Stuff" is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 351(a)(2)(B), in that the methods used in or the facilities or controls used for its manufacture, processing, packing, or holding do not conform with current good manufacturing practices (cGMPs) prescribed in FDA regulations, 21 C.F.R. Parts 210 and 211.

For example:

1. There are no written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess, as required by 21 C.F.R. § 211.100(a). These procedures include procedures relating to the following: charge-in of components, calculation of yield, equipment identification, sampling and testing of in-process materials and drug products, and control of microbiological contamination.

2. Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet appropriate specifications and appropriate statistical quality control criteria as a condition for their approval and release, as required by 21 C.F.R. § 211.165(d). Specifically, there are no criteria for the release of your drug product.

3. Production and control records are not reviewed and approved by the quality control unit to determine compliance with all established approved written procedures before a batch is released or distributed, as required by 21 C.F.R. § 211.192. For example, the Gel Formulating records for lots 60-02G and 14-02G9 do not indicate that they were reviewed and approved by the quality control unit.

4. There are no laboratory controls (such as the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures) designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity, as required by 21 C.F.R. § 211.160(b). For example, there is no written methodology for sampling and testing the finished product for microbial contamination. There is no thermometer for the incubator used for microbial testing.

5. There are no written laboratory control specifications including sampling and testing for in-process materials, as required by 21 C.F.R. § 211.160(b)(2). The Gel Formulating records for lots 60-02G and 14-02G9 indicate an in process step, "pH before set," but there is no written laboratory control description for the pH determination and no logs or records of testing performed.

6. Records are not kept of the cleaning, sanitizing, and inspection of equipment, as required by 21 C.F.R. § 211.67(c).

7. There are no written procedures designed to assure that correct labels, labeling, and packaging materials are used for your drug products, as required by 21 C.F.R. § 211.130.

8. Adequate ventilation is not provided [21 C.F.R. § 211.46(a)]. For example, in the production room on June 24, 2002, there was an open mixing vessel from which product was being packaged. Nearby, an unscreened exterior door was open to the outside

9. There is no written testing program designed to assess the stability characteristics of your drug products, as required by 21 C.F.R. § 211.166(a).

10. Employees engaged in the manufacture, processing, packing, or holding of your drug products lack the training required to perform their assigned functions as required by 21 C.F.R. § 211.25. For example, the laboratory staff was not knowledgeable in performing microbial testing of finished product including proper sampling technique and plating.

This letter is not intended to list all of the deficiencies at your firm. It is your responsibility to assure that your manufacturing operations comply with the requirements of the Act. Failure

to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure of your products and/or a court order prohibiting you from continuing to violate the Act.

In addition, FDA advises other federal agencies of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

We received your response letter dated June 25, 2002, regarding the Inspectional Observations noted on the FDA-483; however, the details of the improvements you have undertaken were not provided. Please advise this office as to the *specific* actions you have taken or intend to take to correct these violations within fifteen days of your receipt of this letter. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to the attention of Thomas S. Piekarski, Compliance Officer, at the address noted on the letterhead.

Sincerely,

Charles M. Breen
District Director